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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/106,390	06/26/98	THOMSON	J 96-0296-9540

CARL R. SCHWARTZ  
QUARLES & BRADY  
411 EAST WISCONSIN AVENUE  
MILWAUKEE WI 53202

HM12/0114

EXAMINER

CLARK, D

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

01/14/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/106,390

Applicant(s)

Thomson, James A.

Examiner

Deborah Clark

Group Art Unit

1633

☒ Responsive to communication(s) filed on Dec 6, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-11 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-11 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's declaration, amendment, and response to the previous office action have been received and entered, 12/06/99, paper nos. 8 and 9. Claims 1-11 remain pending.

### ***Sequence Submission***

2. Applicant's replacement diskette has been received and is in compliance with the requirements.

### ***Double Patenting***

3. The previously made rejection under the doctrine of double patenting is withdrawn in view of the terminal disclaimer filed 06/26/98.

### ***Terminal Disclaimer***

4. The terminal disclaimer filed on 06/26/98 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 5,843,780 has been reviewed and is accepted. The terminal disclaimer has been recorded.

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*Drawings*

5. In view of new practice regarding photographs, the drawings are acceptable. Applicants should disregard the previously mailed PTO-948 as the objections have been canceled.

*Claim Rejections - 35 USC § 112*

6. Claims 1-11 stand rejected under 35 USC 112, 1st paragraph for reasons of record. Re-stated, the nature of the claimed invention is human embryonic stem (ES) cells. By definition, embryonic stem cells are able to contribute to all tissues of an animal including the germ cells (see Nichols et al., page 1341, ¶ 1). The state of the art of the claimed invention is not well established, very few species of animal has had true ES cells isolated. As admitted by applicants only rodent ES cells have been fully characterized (see page 7 of the specification). The art of isolating ES cells is highly unpredictable. Cruz et al. list some of the differences in early embryonic development among swine, oxen, horses, goats, and sheep (see Table 1, page 166). Piedrahita et al. observed that porcine and ovine embryos responded differently to the same treatments. Conditions that allowed production of porcine ES-like cell lines did not allow development of ovine ES-like cell lines (see Table 1, page 886, and page 888). Therefore, one cannot extrapolate from procedures shown effective in one species to another species. As demonstrated by the art cited above numerous attempts have been made to isolate ES cells from species other than the mouse, but (other than the porcine ES cells as claimed by Wheeler (copy enclosed)) demonstration that these cells are able to contribute to the germ line is awaited (see

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Clark et al., page 250, ¶2). The guidance set forth in the specification is not sufficient to enable one of skill in the art to isolate human cell lines. The specification sets forth a procedure for the isolation of primate ES cells. However, this procedure has been shown as successful only as far as the demonstration of certain markers, expression of chorionic gonadotropin, and differentiation into cells representative of each of the three layers of the embryonic germ layers when injected into SCID mice for two species, rhesus macaques and marmosets. No data is set forth regarding humans, which is specifically claimed. And, no data demonstrates that the rhesus or marmoset "ES cells" can contribute to the germline. The amount of experimentation required to practice the claimed invention is paramount. It is not clear that the procedure used in the monkey species would be successful in the human species. In addition, the amount of experimentation required to demonstrate that ES-like cells are true ES cells is vast because the ES-like cells would need to be implanted into a blastocyst, allowed to grow to term, and then demonstrated to have true mosaicism in all tissues including germ line cells.

For these reasons, it was concluded that it would require undue experimentation to make and use the claimed invention.

In response to this rejection applicants have filed a declaration comprising a reference with data which demonstrates that pluripotent human embryonic cells were isolated and that these cells differentiated into trophoblasts and derivatives of all three embryonic germ layers. It is acknowledged that the data supplied correlates with the data supplied in the specification using monkey embryonic cells. However, the data do not demonstrate that the cells contribute to germ

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line cells, which is explicitly discussed above and in the previous office action. Therefore, the cells isolated by applicants cannot be considered human ES cells without a demonstration that the cells will contribute to the germ cells. Further, though the examiner suggested that this data be filed, the examiner did not state that the data would overcome the rejection made under 35 USC 112, 1st paragraph. Rather, the examiner made the comment in the conclusion section because the data in the specification demonstrated only monkey cells whereas the claims specify that the cells are of human origin. In conclusion, the rejection is maintained for reasons of record.

7. The rejections made previously under 35 USC 112, 2nd paragraph are moot in view of applicant's amendment.

### *Conclusion*

8. No claim is allowed.
9. The claims are free of the prior art of record as discussed previously.
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Clark whose telephone number is (703) 305-4051. The examiner can normally be reached on Mondays-Fridays from 7:10 a.m. EST to 3:40 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*Deborah Clark*  
DEBORAH J. CLARK  
PATENT EXAMINER